

KING & SPALDING LLP

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**The 340B Drug Pricing Program:
Overview from the Manufacturers' Perspective**

John D. Shakow
jshakow@kslaw.com
202-626-5523

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Agenda

- 340B Program Basics
- 340B Pricing and Beneficiaries
- 340B Reports and Litigation
- The Future of 340B

340B Program Basics

The Veterans Health Care Act of 1992

- Title VI passed in November 1992 in response to the Omnibus Budget Reconciliation Act of 1990, which created the Medicaid rebate system
- As FSS and PHS entities were not best price exempt, manufacturers raised prices offered to them
- Three sections:
 - 601 Changes to Medicaid Rebate Program
 - 602 Special pricing for PHS Covered Entities

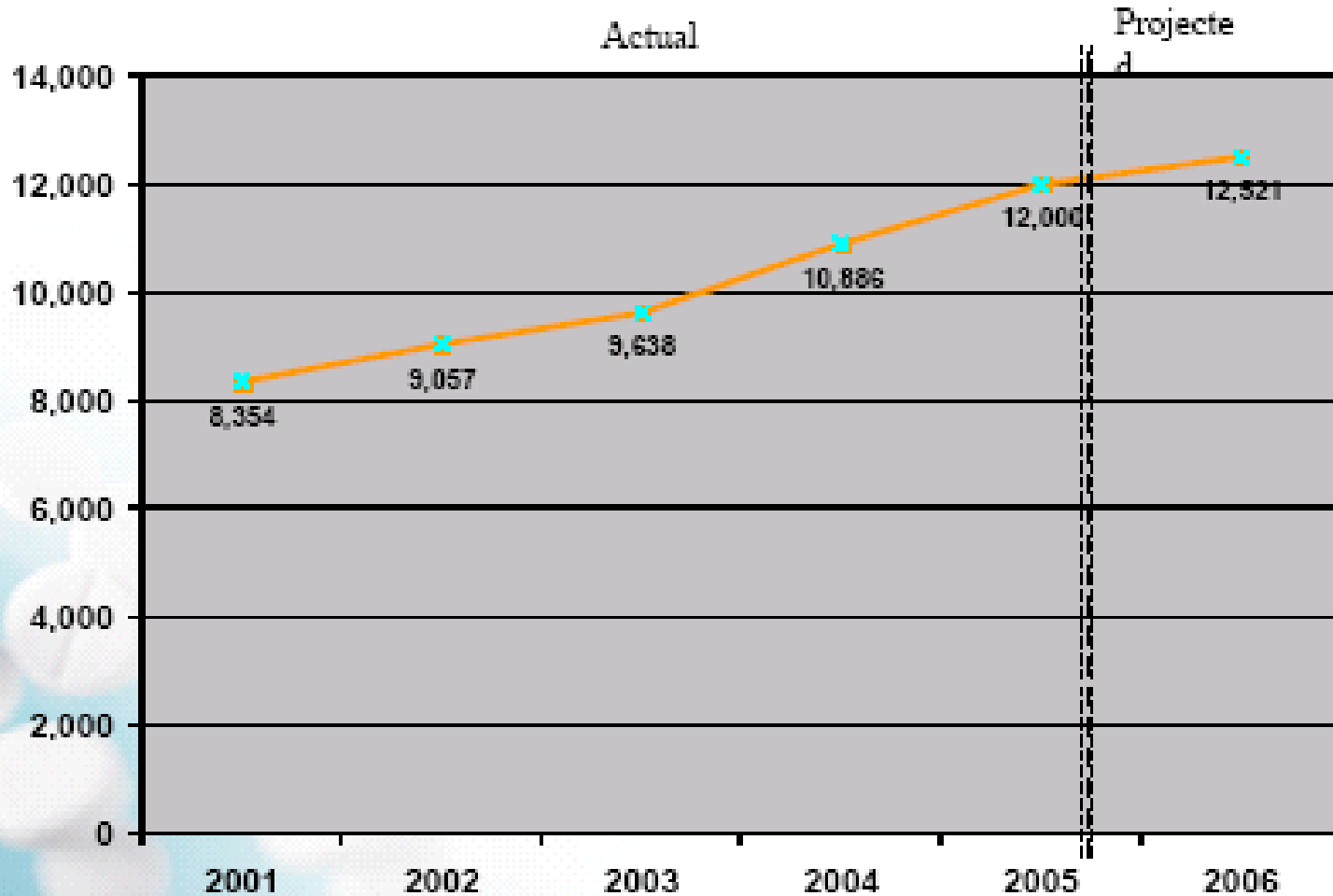
VHCA Section 602

- Amended PHS Act – 42 U.S.C. § 256b
- “Limitation on prices of drugs purchased by covered entities”
- The statute
 - Manufacturer agreement with the Secretary of HHS
 - Ceiling price
 - Covered outpatient drugs only
 - Covered entities

All together now

- PHS ceiling price
- 340B ceiling price
- Section 602 ceiling price
- Public Law 102-585

Number of Covered Entity sites – All Types



Source: HPPI presentation

Government Oversight

- Human Resources and Services Administration (HRSA)
- Healthcare Systems Bureau (HSB)
- Office of Pharmacy Affairs (OPA)
 - Manages contracts with manufacturers
 - Manages enrollment of covered entities
 - Formerly the Office of Drug Pricing
 - Formerly the Pharmacy Affairs Branch
 - OPA Director Jimmy Mitchell
 - Excellent website: www.hrsa.gov/opa

Importance of 340B

- Serves uninsured low income populations
- Public health systems critical to reaching underserved areas and disease states
- PHS purchasing saves Medicaid systems millions of dollars every year by billing at acquisition cost, not a reimbursement amount based on AWP

340B Pricing and Beneficiaries

340B Ceiling Price

- Discount version of a Medicaid rebate
- Ceiling price, determined quarterly: AMP less the Unit Rebate Amount for the most recently reported quarter
- Branded URA = $AMP \times 15.1\%$ or $AMP - BP$
- Generic URA = $AMP \times 11\%$
- Recall that this is just a ceiling – manufacturers may offer sub-ceiling prices that are still best price exempt

340B Ceiling Price

- Manufacturers calculate the ceiling price to effectuate sales – they need not report them
- The government separately calculates the ceiling price to aid in program oversight, but does not actively check against the manufacturers' price lists
 - CMS
 - Since last month, HRSA per inter-agency agreement
- The covered entities do not have access to the AMP or URA, and therefore can do no independent check of the calculated ceiling

Package Size

- AMP, BP and URA are calculated based on Medicaid rebate units, that is, the smallest dispensable unit (e.g., pill, blister pack, etc)
- Covered entities purchase (or seek rebates) at a package size
- Gross up URA to package size to determine actual price (or rebate) per NDC-11
- OPA wants manufacturers to volunteer package size information directly, so that it does not have to go to publishers to get it

340B Ceiling Price for New Drugs

- Use “Estimated Ceiling Price” until actual data is known – 3 quarters
- For example:
 - Launch mid 1Q05
 - First full quarter is 2Q05
 - Base quarter data known July 30, 2005
 - Actual PHS price set and offered in 4Q05
- Where estimated $>$ ceiling, manufacturers must reconcile upon request
- Where estimated $<$ ceiling, that’s a sub-ceiling

Changes to AMP or BP and the 340B Ceiling Price

- Only written guidance on this issue is in the context of new drugs
- Where a manufacturer has a retrospective change in methodology and pursues significant revisions to AMP and BP under Releases 14 and 61, OPA expects the PHS price to be revised and overcharges reconciled
- What is unclear is at what threshold of ceiling price change reconciliation is required
- Routine true-ups to AMP and BP? De minimus changes to the ceiling price? Only upon request?

340B Prime Vendor Program (PVP)

- Purposes:
 - Negotiate sub-ceiling discounts for CEs
 - Offer CEs drug distribution options
- Manufacturers must participate (PPA II(g))
- HealthCare Purchasing Partners Intl. (HPPI) (a GPO)
- Represents 1,750 CEs purchasing over \$2 billion
- Discounts range from 1% to 49% below ceiling
- Claims to offer best price protection

340B Covered Entities

- Certain facilities or programs funded by HRSA (as set out in 42 U.S.C. §256b)
 - Federally-qualified health centers
 - Certain federal grant recipients
 - Family planning clinics
 - AIDS Drug Assistance Programs (ADAPs)
 - Black lung clinics
 - Hemophilia treatment centers
 - Native Hawaiian Health Centers
 - Urban Indian organizations

Tuberculosis/STD clinics

340B Covered Entities

- Disproportionate share hospitals owned by or under contract with state or local governments
 - Disproportionate share adjustment percentage greater than 11.75%
 - May not utilize a GPO for outpatient drug purchasing
 - Inpatient v. outpatient segregation
- Sales to covered entities are exempt from best price

340B Covered Entities

- Other requirements for covered entities
 - May not double-dip with Medicaid
 - May not resell to a non-patient (diversion)
- Three part “patient” test
 - Entity-patient relationship
 - Entity retains responsibility for care
 - Entity provides services consistent with those for which grant funding was given

340B Covered Entities: Manufacturer / CE Conflict

- Manufacturers may audit any covered entity that purchased its drugs at 340B program prices
- Use of the informal dispute process encouraged by OPA
- Details of each at 61 F.R. 65406

340B Covered Entities: Manufacturer Tracking

- Entities bear affirmative obligation to become and remain CEs (and to ask for price)
- Manufacturers bear affirmative obligation to give all CEs the 340B ceiling price or below
- Manufacturers that fail to track fall-offs run the risk of setting new best prices
- HRSA website:
<http://opanel.hrsa.gov/opa/Login/MainMenu.aspx>

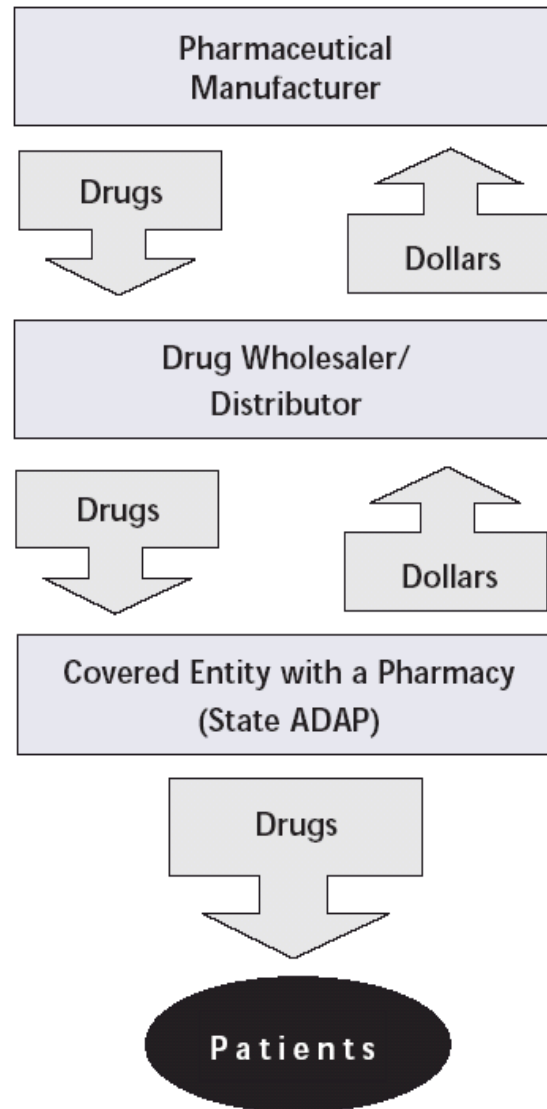
340B Covered Entities: Manufacturer Tracking

- Manufacturers need to monitor who is entitled to purchase off the 340B contract, and when
- Treat like commercial GPO contracts
- Do not rely on the wholesaler to police – review before chargebacks are processed
- Burn a CD of the HRSA list every quarter for internal use and recordkeeping

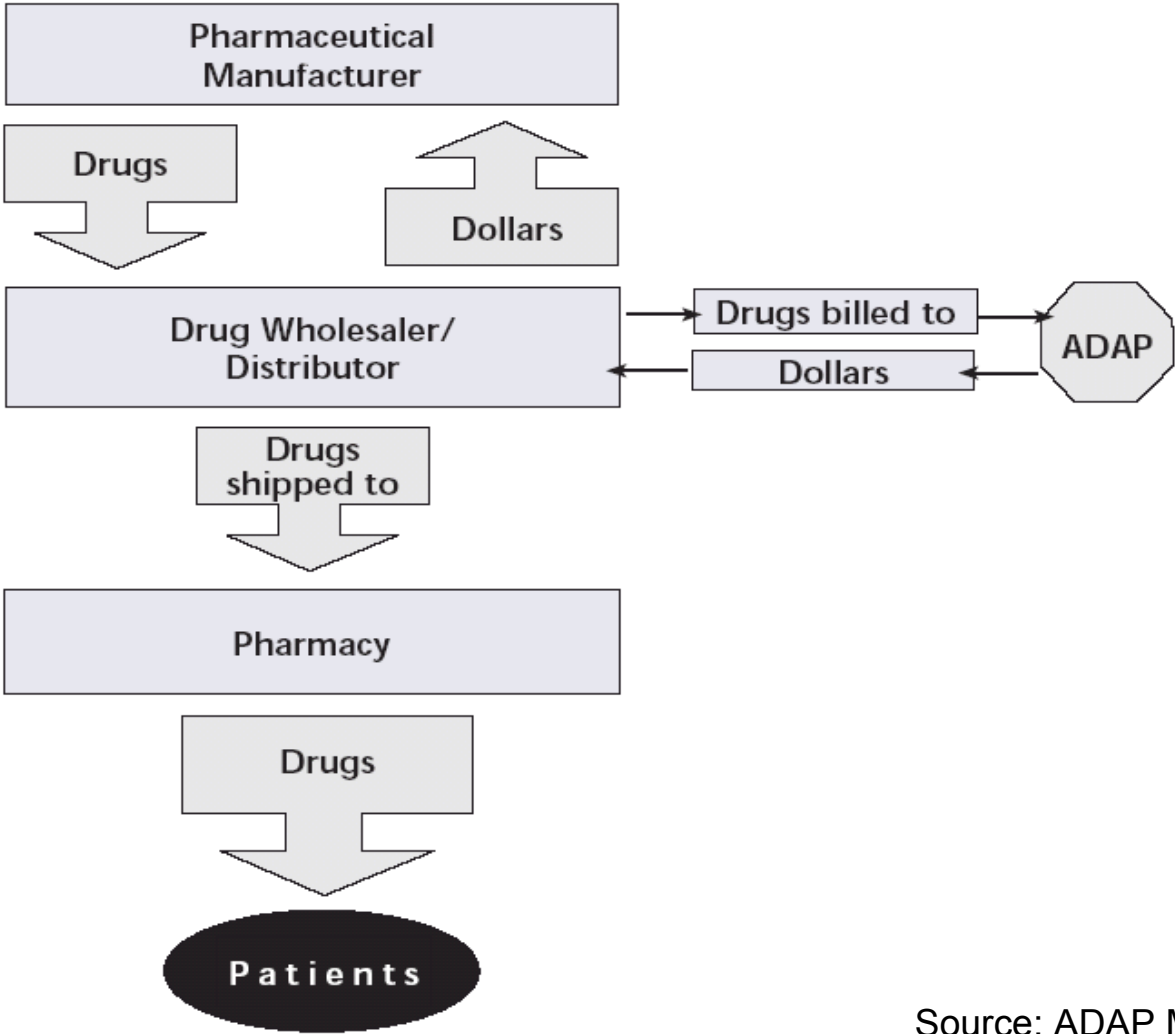
340B Sales Channels

- Direct sales to CEs at ceiling price or below
- Indirect sales through a wholesaler
 - PVP contract
 - Other contract
- Contract pharmacy
- Rebate program for ADAPs only

How the Point of Purchase Discount System Works

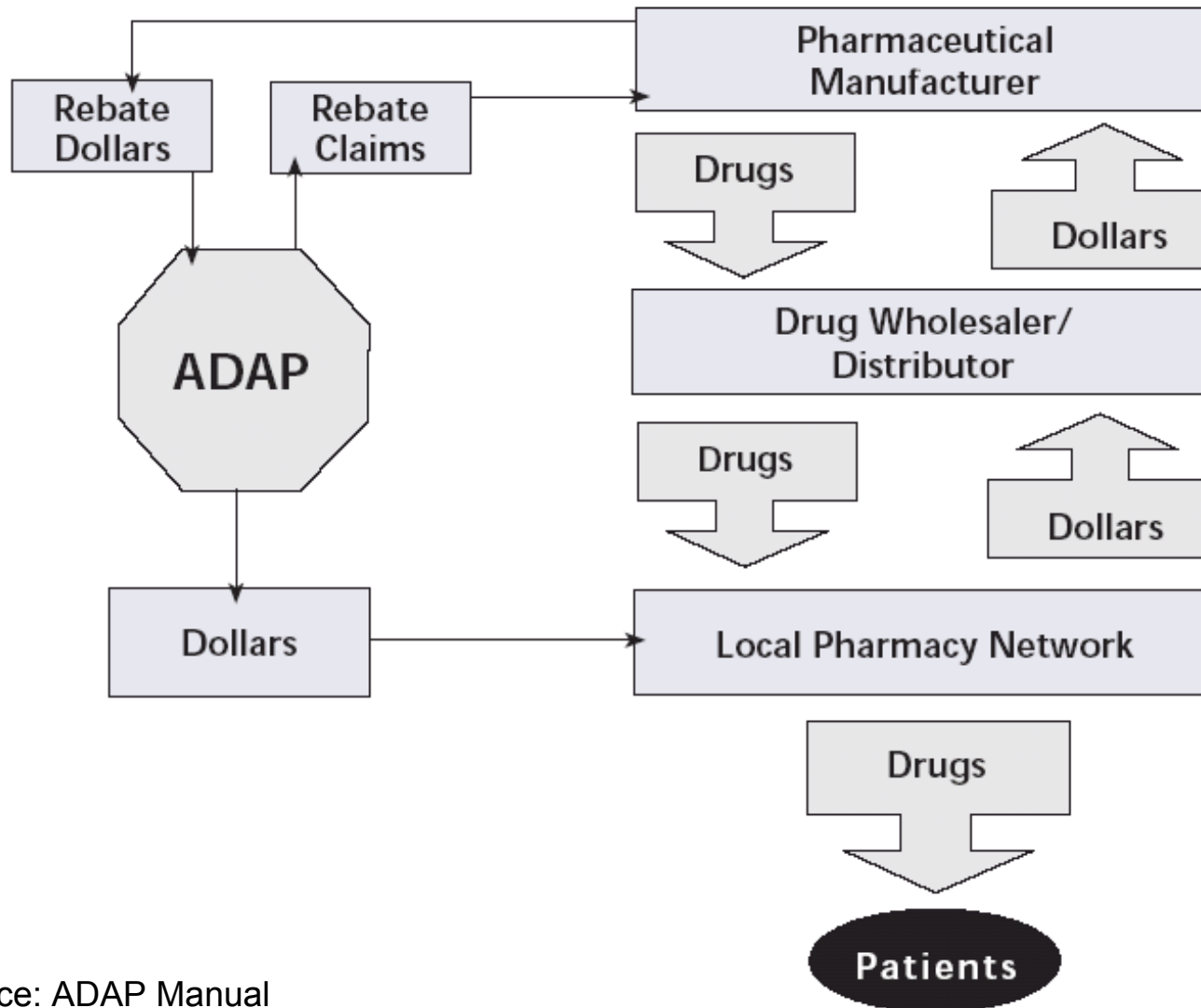


How the contract pharmacy system works



Source: ADAP Manual

HOW THE ADAP 340B REBATE OPTION WORKS



Source: ADAP Manual

ADAP Rebate Program

- Very much like a Medicaid rebate
- ADAP has to elect to participate
- “Partial pay for full rebates” question
 - ADAPs may pay co-pays, deductibles, premiums
 - Until April 29, 2005, pro-rated rebates (Q. 29)
 - April 29, 2005 letter from HIV/AIDS Bureau granted full rebates for partial pay claims (co-pay or deductible whether or not premium is also paid)
 - Profit center for ADAPs?

340B Reports and Litigation

OIG Reports

- March 2003: “Pharmaceutical Manufacturers Overcharged 340B Covered Entities”
- June 2004: “Deficiencies in the 340B Program’s Database”
- June 2004: “Appropriateness of 340B Drug Prices” *withdrawn* October 2004
- October 2005: “Deficiencies in the Oversight of the 340B Drug Pricing Program”
- Spring 2006: expected re-issuance of “Appropriateness of 340B Drug Prices”

OIG Reports

- The withdrawn June 2005 report said that:
 - Almost a third of sampled prices were above the 340B ceiling
 - 36 of the 37 sampled entities had made payments in excess of the ceiling
 - CEs were overpaying \$41.1 million per month
- There were significant problems that caused the June 2005 report to be withdrawn:
 - CMS provided OIG with data from the wrong timeframe

OIG Reports

- Findings of the October 2005 report:
 - CMS and HRSA lack effective communications and controls regarding ceiling prices
 - HRSA lacks sufficient authority to ensure that CEs pay at or below the ceiling price
 - HRSA has no mechanisms in place to compare its ceiling prices with those released by the manufacturers
 - CEs cannot verify the ceiling prices they are being offered due to concerns regarding confidentiality

OIG Reports

- Recommendations of the October 2005 report:
 - CMS and HRSA should cooperate to create an accurate and timely record of ceiling prices
 - HRSA should develop detailed SOPs regarding ceiling price calculation
 - HRSA should check the list of prices being offered by:
 - Comparing government and manufacturers prices
 - Spot check CE invoices

340B Lawsuits

- *Central Alabama Comprehensive Healthcare v. Aventis et al* (N.D. Ala. 2004)
 - Nationwide class of CEs who claim, based on the June 2004 OIG report, that they have been overcharged
 - Counts: Accounting, Breach of Contract, Unjust Enrichment
 - Report withdrawn October 2004
 - Motion to dismiss denied September 2005
- *Santa Clara County v. Astra USA et al* (N.D. Cal. 2005)

The Future of 340B

Pending Legislative Action

- Senate Finance Committee (Grassley) has been inquiring about manufacturers' compliance with the 340B program
- Senate and House bills would affect the 340B program:
 - House bill would make 75 children's hospitals eligible for 340B pricing
 - Senate bill would increase the rebate percentage for both branded and generic drugs to 17%, lowering the 340B ceiling price for many drugs
 - Senate bill would also require authorized generics' best prices to be included in branded's best price, lowering the 340B ceiling price for many drugs

Questions Confronting the 340B Program

- What will the revised OIG report say about the prices actually received by 340B entities?
- Will the 340B litigation spawn similar lawsuits around the country?
- How will the tension between 340B oversight and confidentiality of AMP and BP be resolved?
- How will HRSA reform its operations in response to the OIG criticisms?

Questions Confronting the 340B Program

- Will the rebate option be extended to PHS CEs other than ADAPs?
- How will OPA and HRSA resolve the “partial pay for full rebate” question?
- How will OPA come down on revisions to AMP and BP – what will be considered a threshold change requiring PHS price reconciliation?

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**For further information, please feel free
to call or e-mail.**

John Shakow

jshakow@kslaw.com

202-626-5523